BULKING AGENT NEEDLE APPARATUS AND METHOD OF USING THE NEEDLE APPARATUS

BACKGROUND

This invention provides an apparatus, method and kit for injecting bulking agents into tissues surrounding the sphincter regions of organs, such as injecting bulking agents into tissue planes between the esophagus, rectum or urethra and the adjacent or surrounding sphincter muscles, to treat sphincter deficiencies associated with these organs. For example, bulking agents may be injected into a soft tissue plane between the urethra and the surrounding sphincter muscles to treat stress urinary incontinence. Injecting or adding bulking agents to such tissues generally serves to augment the gastric, rectal or urinary sphincter mechanisms.

The percutaneous injection of bulking agents into tissues to augment, support, or reconfigure anatomic structure has been the subject of significant research and product development. Procedures have been reported in medical literature for correction of dermatological and otolaryngological problems and for treatment of urological disorders. For example, Walker et al., "Injectable Bioglass as a Potential Substitute for Injectable Polytetrafluoroethylene," *J. Urol.*, 148: 645-7 (1992) reports using a particular bioglass material as a bulking agent.

An example of this type of procedure using injectable bulking agents for treating urological disorders, particularly urinary incontinence, has been reported. Incontinence occurs when the resistance to urine flow has decreased to the point where the resistance can no longer withstand the intra-abdominal pressure. Nearly all procedures developed to restore continence are based on restoring the lost resistance to urine outflow. U.S. Pat. Nos. 5,007,940; 5,158,573; and 5,116,387 to Berg report biocompatible compositions comprising discrete, polymeric and silicone rubber bodies injectable into urethral tissue for the purpose of treatment of urinary incontinence by tissue bulking. Further, U.S. Pat. No. 5,451,406 to Lawin reports biocompatible compositions comprising carbon coated particulate substrates that may be injected into a tissue, such as the tissues of and that overlay the urethra and bladder neck, for the purpose of treatment of urinary incontinence by tissue bulking.

One concern or adverse consequence associated with methodologies or therapies of tissue bulking relates to the migration of solid particles in the bulking agents from the original site of

placement into repository sites in various body organs and the subsequent chronic inflammatory response of tissue to particles that are too small. These adverse effects are reported in urology literature, specifically in Malizia, A.A., et al., "Migration and Granulomatous Reaction After Periurethral Injection of Polytef (Teflon)," *JAMA*, 251:3277-3281 (1984) and in Claes, H., Stroobants, D. et al., "Pulmonary Migration Following Periurethral Polytetrafluoroethylene Injection For Urinary Incontinence," *J. Urol.*, 142:821-822 (1989).

An important factor in assuring the absence of migration is the administration of properly sized particles. If particles are too small, they may be engulfed by the body's white cells (phagocytes) and carried to distant organs or may be carried away in the vascular system and travel until they reach a site of greater constriction. Target organs for particulate deposition include the lungs, liver, spleen, brain, kidney, and lymph nodes. The use of small diameter particulate spheres and elongate fibrils in an aqueous medium having biocompatible lubricant have been disclosed in Wallace et al., U.S. Pat. No. 4,803,075. While these materials showed positive, short term augmentation results, this result was short lived as the material had a tendency to migrate and/or be absorbed by the host tissue. Small diameter particles can also produce chronic inflammatory response in tissue, and have been associated with clinical complications.

Similarly, particles that are too large are also generally unsuitable. Because various treatment methods typically inject a specific tissue site with particles suspended in a carrier fluid using an hypodermic needle, large particles are typically more difficult to deposit. In particular applications or methods, large particles will not pass through an appropriately or suitably sized hypodermic needle, will require too much pressure to be placed at a specific tissue site or will be unevenly distributed in or separate from the carrier fluid at the injection site.

In addition, proper particle and bulking agent placement is also important to the success of tissue bulking procedures. For example, when treating stress urinary incontinence, the bulking agent is typically injected into the soft tissue plane between the urethra and the surrounding muscles using a hypodermic needle. In some cases, the needle may be difficult to place as it must be inserted past the external urethral sphincter while limiting its penetration depth so as to avoid penetrating the urethra or bladder. In other cases, the needle may be improperly placed in muscle tissue which results in excessive pressure to deposit the bulking agent or separates the bulking agent from the carrier fluid. In still other cases, the needle may be

improperly placed in a vein or artery which may lead to migration of the bulking agent via the vascular system. In sum, the success of the procedure depends on accurate insertion and placement of the needle so as to inject the bulking agent into the desired soft tissue site.

Thus, there remains a need for a suitable methods and procedures that improve positional accuracy of the injected bulking agent in order to provide a lasting remedy for the treated patient.

SUMMARY OF THE INVENTION

This invention provides an apparatus for injecting bulking agents into tissues adjacent to or surrounding the sphincter regions of the esophagus, rectum or urethra. When used, such an apparatus enables injecting bulking agents into tissue planes between an organ and adjacent or surrounding sphincter muscles in order to treat sphincter deficiencies and related conditions associated with such deficiencies. The apparatus is a syringe and a hypodermic needle having both linear and arcuate segments. The hypodermic needle is sufficiently rigid so as to maintain both the linear and arcuate segments, but retains a minimal amount of flexure to aide in the proper insertion and positioning of the needle in the tissue. A penetration depth shield or guide may be added to the linear portion of the hypodermic needle to limit the penetration of the needle into the desired tissues or tissue planes and to aid insertion and control of the needle to aid in the proper positioning of the needle. In use, the syringe contains an injectable nonabsorbable bulking agent used to treat sphincter deficiencies and associated related undesired conditions.

The present invention also includes a method for injecting a bulking agent into the soft tissue plane between an organ, such as an esophagus, rectum or urethra, and the surrounding muscle by using a hypodermic needle having both linear and arcuate segments and a syringe containing a bulking agent. The hypodermic needle may also include a penetration depth shield or guide located on the hub or on the linear segment of the needle. In one embodiment, the method includes injecting a bulking agent into the soft tissue planes between the urethra and the surrounding sphincter muscles and further includes locating the periurethral sinus and penetrating the tissue with a needle, then advancing and positioning the needle using the arcuate segment of the needle and the penetration depth shield or guide to aid proper placement of the needle at the desired tissue site. The method further includes attaching the syringe to the needle and injecting a suitable bulking agent into the soft submucosal tissue surrounding the urethra. In one embodiment of this method, the bulking agent may be comprised of a plurality of discrete,

nonabsorbable carbon coated particles that are carried in a fluid and lubricative biocompatible medium.

In another embodiment, a needle kit for treating stress urinary incontinence is provided. The needle kit contains a syringe, a hypodermic needle having both linear and arcuate segments, a penetration depth shield or guide, and an injectable bulking agent. The bulking agent may be a plurality of discrete, carbon coated particles that are carried in a lubricative biocompatible medium.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a perspective view of a needle and syringe in accordance with the present invention.

FIGS. 2 and 3 are perspective views of a needle and penetration depth shield or guide and a needle, penetration depth shield or guide and syringe in accordance with the present invention.

FIG. 4 is a perspective view of a suitable needle hub adapted to be secured to a mated syringe.

FIG. 5 is a diagram of a needle preparing to inject a bulking agent into soft tissues between an urethra and the surrounding muscle to treat stress urinary incontinence in accordance with one embodiment of the present invention.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Referring to the drawings, FIG. 1 illustrates an apparatus 10 for injecting bulking agents into the soft tissue plane between an organ and the adjacent or surrounding muscle. In one example such an apparatus is used to inject a bulking agent into the soft tissue plane between the urethra and surrounding muscle to treat stress urinary incontinence in accordance with the present invention.

Apparatus 10 includes a syringe 11 and a hypodermic needle 12. Hypodermic needle 12 includes a linear segment 13 and an arcuate segment 14. The linear segment 13 extends from the hub 17 of the needle 12 to the arcuate segment 14 that is formed by about a five to about a forty-five degree bend 15 located within the portion of the needle 12 closest to the tip 16. The degree of the bend in the arcuate segment of the needle depends on the particular tissues or tissue sites that will be treated by bulking agent injection. In one embodiment, the bend 15 is about fifteen

degrees and is generally located about 0.75 inches from the tip 16. In alternate embodiments, the bend 15 may be slightly more or slightly less than fifteen degrees, but is kept shallow to reduce the likelihood that the needle 12 will kink, preventing the bulking agent in the syringe 11 from being delivered effectively to the soft tissue site. Keeping the bend 15 shallow also allows for a more direct placement of the needle tip 16 at the preferred injection site and is compatible with both larger and smaller diameter needles. The needle 12 must be sufficiently rigid so as to maintain both the linear and arcuate segments, but preferably retains a minimal amount of flexure to aide in the proper insertion and positioning of the needle 12 in soft tissue. The hub 17 may be configured to mechanically attach or lock with the syringe to prevent separation under pressure and may be made of visually transparent or clear material to ensure that the needle has not been placed in vascular tissue. Once in place, slight back pressure on the syringe would draw back blood if the needle is improperly placed in the vascular system and any withdrawn blood is readily seen at the hub when it is a transparent or clear material.

FIGS. 2 and 3 illustrate the needle and apparatus 10 of FIG. 1 with the addition of a penetration depth shield or guide 18. The penetration depth shield 18 is generally located about 0.75 inches back from the bend 15 toward the hub 17. For needles having a length of about 1.5 inches the penetration shield may be at the hub or may be an integral part of the hub. For longer needles, the penetration depth shield may fit around the bore of the needle and may be sized to aid the handling and control of the needle with the fingers of the physician as it is placed at the desired tissue site. If the bend 15 is located 0.75 inches from the tip 16, the penetration depth shield 18 will limit the penetration of the needle 12 to about 1.5 inches. Limiting the penetration as such prevents the needle tip 16 from perforating the bladder or urethra and aides in proper placement of the needle 12 to inject the bulking agent at the desired soft-tissue site.

The total length of the needle 12 from hub 17 to tip 16 is at least 1.5 inches and for some procedures or uses is less than 5 inches. In alternative procedures or uses, the total length of the needle may be up to 60 inches. Appropriately sized needles for the apparatus and method of some of the embodiments of this invention are 18 gauge (OD-0.050 inches, ID-0.043 inches) or 19 gauge (OD-0.042 inches, ID-0.035 inches) stainless steel needles having a length of about 1.5 inches. The needle tip 16 may be of any one of a number of configurations, with the preferred tip being one that does not core the tissue. In some embodiments, an optional stylet may be used in combination with the needle. As illustrated in FIG. 3, the stylet is a solid shaft that fits into the

needle and has a distal end that is cut flush with the needle's end. The proximate end of the stylet would contain a stop or finger grip. When in place, the stylet prevents tissue form entering the needle as the needle is placed at the tissue site. Once the needle is properly placed, the stylet is removed while the needle is retained at the injection site.

FIG. 4 illustrates a suitable system 40 for injecting suspended solids including a syringe 41 and a hypodermic needle assembly 42. Syringe 41 includes a generally cylindrical body having a distal portion 43 and a threaded region 44. Disposed within the syringe body is a plunger 45 having a distal portion 46 and rubber seals 47. Syringe 41 has a tapered, protruding male member 48 having a lumen 49 therethrough. Protruding member 48, in a preferred embodiment, has a standard Luer taper.

Hypodermic assembly 42 includes a proximal hub 50 and a needle 51. Needle 51 is commonly formed of hypotube and is illustrated having a protective sheath 52 disposed over the needle. Hub 50 includes a threaded cylindrical region 53 having a lumen 54 therethrough. Lumen 54 substantially defines the longitudinal axis of hypodermic needle assembly. Threaded cylindrical region 53 includes an inner wall surface 55, preferably having a standard Luer taper adapted to mate with syringe member 48. In the hub threaded region, a preferred embodiment has more than one start thread, to provide additional sealing force over the length of threaded regions 53 and 44 when tightened. In the embodiment of FIG. 4, the hub threaded region has two start threads, with one start indicated at 56 and the other disposed 180 degrees opposite. In this embodiment, each of the two threads wraps 1 and ½ turns about the hub. The hub includes two wings 57, each having a thinner, internal portion 58, and a thicker, rounded, peripheral rib portion.

FIG. 5 shows the needle 12 and penetration depth shield 18 of FIGS. 2 and 3 preparing to inject a bulking agent into the soft tissue plane between the urethra 20 and the sphincter muscle 21 to treat stress urinary incontinence according to one embodiment of this invention. To perform this particular procedure, the needle 12, penetration depth shield 18 and syringe, containing a suitable bulking agent, are prepared and primed. Using standard procedures, a patient is prepared for a cystoscopy and a cystoscope 22 is inserted into the urethra 20 up to the bladder neck 23. After locating the periurethral sinus 24 at the lateral border of the medial lip, the needle 12 is inserted into the tissue at either the 3 o'clock or 9 o'clock position of the periurethral sinus 24 and is advanced slowly until it penetrates past the external sphincter 25,

using the cystoscope image as a guide. The bend 15 in the needle 12 is used to guide the needle 12 in an arc to the submucosal tissue 26 between the urethra 20 and the muscle plane 21.

To verify proper placement of the needle 12 within the submucosal tissue 26, the position of the penetration depth shield 18 should be noted close to the periurethral tissue 24 and the cystoscope image may be viewed while gently moving the needle 12 within the tissue. If only the local area at the needle tip 16 moves, the needle 12 is properly positioned within the submucosal tissue 26. If the entire urethra 20 moves, the needle tip 16 may be in muscle and must be repositioned by pulling back the needle 12 slightly and again verifying placement using the cystoscope 22 and the position of the penetration depth shield 18. After the needle 12 is properly positioned within the submucosal tissue 26, the syringe containing a bulking agent is attached to the needle 12 and the bulking agent is injected into the submucosal tissue 26, forming a bleb.

The bulking agent may be one of several compositions, but in one embodiment the bulking agent is a plurality of discrete, nonabsorbable, carbon coated particles in a carrier. The carrier itself is preferably a biocompatible medium having lubricative qualities and sufficient fluidity to carry and deliver the particles. One such carrier is ß-glucan, a naturally occurring constituent of cell walls in essentially all living systems. ß-glucan is rapidly removed from tissue sites through macrophage phagocytosis or by enzymatic destruction by serous enzymes, instigating an interaction between the particles and tissue. Aqueous solutions, suspensions, fluids, or gels of ß-glucan may be produced that have favorable physical characteristics as a carrier for carbon-coated particles. The viscosity can vary from a thin liquid to a firm, self-supporting gel. Irrespective of viscosity, the ß-glucan has excellent lubricity, thereby creating a particle-carrier composition that is easily administered by delivery to a predetermined tissue site through a small-bore needle. The rapid removal of ß-glucan, as well as its available viscosity and lubricous nature, make it an optimum carrier for the particles.

The particles are microbeads or microparticles of a hard material serving as a substrate and having a thin coating or film of biocompatible, isotropic carbon deposited on their surfaces. Different types of carbon coating processes may be utilized, but the desired result is a smooth-coated particle with no substrate exposure on the surface of the particle or in contact with tissue when injected. The particles must be large enough so as to discourage local and distant migration once injected, yet small enough so as to be administered by hypodermic needle. Thus,

particles with an average transverse cross-sectional dimension of between 100 and 1,000 microns, or between 200 and 500 microns if the particles are of generally rounded shape, are preferred.

To facilitate the treatment of stress urinary incontinence, a kit has been assembled in accordance with the present invention. The kit includes a syringe, a hypodermic needle having both linear and arcuate segments, a penetration depth shield, and an injectable bulking agent to be used to treat stress urinary incontinence by way of tissue bulking. The bulking agent is preferably a plurality of particles in a carrier, where the carrier is a biocompatible medium having lubricative qualities and sufficient fluidity to carry and deliver the particles. The particles themselves are preferably discrete carbon coated particles having an average transverse cross-sectional dimension of between 100 and 1,000 microns, or between 200 and 500 microns if the particles are of rounded shape.

Although the present invention has been described with reference to preferred embodiments, those skilled in the art will recognize that changes may be made in form and detail without departing from the spirit and scope of the invention.

What is claimed is: